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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,463	06/29/2001	A.K. Gunnar Aberg	559P019	6535
7:	590 09/26/2003			
Kevin S. Lemack			EXAMINER	
Nields & Lemack Suite 8			JONES, DWAYNE C	
176 E. Main St	reet			
Westboro, MA	01581		ART UNIT	PAPER NUMBER
			1614	
			DATE MAILED: 09/26/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N .	Applicant(s)				
Office Action Summary		09/895,463	ABERG, A.K. GUNNAR				
		Examiner	Art Unit				
		Dwayne C Jones	1614				
	The MAILING DATE of this communication appears on the cover sheet with the cerrespendence address						
Period for Reply							
THE I - Exter after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period or re to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply to within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS cause the application to become ABAND	be timely filed I days will be considered timely. Ifrom the mailing date of this communication. ONED (35 U.S.C. § 133).				
1)	Responsive to communication(s) filed on						
2a)☐		is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disp sition of Claims							
•	4) Claim(s) 1-17 is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
· · · · · · · · · · · · · · · · · · ·	6) Claim(s) <u>1-17</u> is/are rejected.						
·	7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers							
·· _	·	r					
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1.☐ Certified copies of the priority documents have been received.							
	Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Inform	mary (PTO-413) Paper No(s) mal Patent Application (PTO-152)				

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DETAILED ACTION

Status of Claims

1. Claims 1-17 are pending.

2. Claims 1-17 are rejected.

Information Disclosure Statement

- 3. The information disclosure statement filed September 9, 2001 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.
- 4. The information disclosure statement filed September 9, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 6, 11, 12, 13, 14, 15, 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johansson et al. of U.S. Patent No. 5,559,269. Johansson et al.

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teach of the compounds of general formula I, (see column 1, lines 12-59 and column 2, lines 1-20). Johansson et al. also teach that these compounds is used in the treatment of acetylcholine-mediated disorders, namely urinary incontinence. In addition, Johansson et al. disclose that a daily dosage from about 0.05 mg to about 200 mg daily, (see column 5, lines 55-65). Johansson et al. also teach of administering these compounds in various forms, namely oral and parenteral administration, (see column 5, lines 50-54). Even though the claims purport that there is a reduction or an elimination of concomitant liability of adverse side effects associated with the parent compounds, the courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art."

7. Claims 6, 11, 12, 13, 14, 15, 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johansson et al. of U.S. Patent No. 5,686,464. Johansson et al. teach of the compounds of general formula I when the variables of R¹, R², and R³ each represent hydrogen and the variable of X represents N(CH(CH₃)₂)₂ and specifically the compound of Example 1, (see abstract, and columns 1-2, and column 6). Johansson et al. also teach that these compounds is used in the treatment of acetylcholine-mediated disorders, namely urinary incontinence. In addition, Johansson et al. disclose that a daily dosage from about 0.05 mg to about 200 mg daily, (see column 5, lines 55-65). In addition, Johansson et al. disclose of the optical isomers, the racemic mixture as well as the individual isomers as such, (see column 1, lines 57-59). Despite the fact that the claims purport that there is a reduction or an elimination of concomitant liability of

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adverse side effects associated with the parent compounds, the courts have held, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, see *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claims 1, 4, 5, 6, and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansson et al. of U.S. Patent No. 5,686,464. Johansson et al. teach of the compounds of general formula I when the variables of R¹, R², and R³ each represent hydrogen and the variable of X represents N(CH(CH₃)₂)₂ and a hydrocarbyl group, such as a methyl group, and specifically the compound of Example 1, (see abstract, and columns 1-2, and column 6). Moreover, Johansson et al. teach

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Johansson et al. also teach that these compounds is used in the treatment of acetylcholine-mediated disorders, namely urinary incontinence. In addition, Johansson et al. disclose that a daily dosage from about 0.05 mg to about 200 mg daily, (see column 5, lines 55-65). In addition, Johansson et al. disclose of the optical isomers, the racemic mixture as well as the individual isomers as such, (see column 1, lines 57-59). Despite the fact that the claims purport that there is a reduction or an elimination of concomitant liability of adverse side effects associated with the parent compounds, the courts have held, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, see In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). It is well within the level of the skilled artisan to substitute a methyl group for a hydrogen atom. In this case, this compound, as claimed by applicant, would be a structural analog of the compounds disclosed by Johansson et al. One having ordinary skill in the art would have been motivated to select the claimed compound with the expectation that substitution of a methyl group for a hydrogen atom would not significantly alter the analogous properties of the compound of the reference due to close structural similarity of the compounds. Accordingly, for those instant compounds that have a hydrogen atom in lieu of the prior art methyl group attached to the nitrogen atom, the skilled artisan would have been motivated to select these due to the close structural similarity. 11. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansson et al. of U.S. Patent No. 6,313,132. Johansson et al. disclose of the

diarylpropylamine compounds of general formula I for the treatment of urinary

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incontinence, (see columns 1 and 2, as well as column 4, lines 52-54). Due to the fact that the variable of R4 is methyl as well as a hydroxymethyl group as well as the variables of R⁶ and R⁷ being equal to hydrocarbyl groups, such as methyl, one having ordinary skill in the art would have been motivated to select the claimed compound with the expectation that substitution of a methyl group for a hydrogen atom would not significantly alter the analogous properties of the compound of the reference due to close structural similarity of the compounds. Despite the fact that the claims purport that there is a reduction or an elimination of concomitant liability of adverse side effects associated with the parent compounds, the courts have held, the claiming of a new use. new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, see *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Moreover, Johansson et al. teach Johansson et al. also teach that these compounds is used in the treatment of acetylcholine-mediated disorders, namely urinary incontinence. In addition, Johansson et al. disclose that a daily dosage from about 0.05 mg to about 200 mg daily, (see column 9).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

Tech. Otr. 1614

September 20, 2003